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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products  
Liability Litigation

No. MD-15-02641-PHX-DGC

DORIS JONES and ALFRED JONES, a  
married couple,

Plaintiffs,

v.

C.R. BARD, INC., a New Jersey  
corporation and BARD PERIPHERAL  
VASCULAR, an Arizona corporation,

Defendants.

**RESPONSE TO DEFENDANTS' BRIEF  
REGARDING RECONSIDERATION OF  
ISSUES DECIDED IN THE *BOOKER*  
MATTER**

(Assigned to the Honorable David G.  
Campbell)

**(Oral Argument Requested)**

Plaintiff Doris Jones briefly responds to Defendants' Brief Regarding Reconsideration of Issues Decided in the Booker Matter [Doc. 10677] ("Brief"). For the reasons stated below, Bard's request to exclude evidence of Recovery filter complications and development (Brief, Part A), Recovery filter cephalad migration deaths (Brief, Part B) and FDA Warning Letter evidence (Brief, Part C) should be denied.

**I. As in *Booker*, Recovery Filter Evidence is Relevant.**

Bard seeks to exclude evidence of the Recovery filter's development, complications, and deaths associated with those complications as both irrelevant (as to

1 development and complications) and unduly prejudicial (as to deaths associated with  
2 cephalad migration). Bard suggests that the Recovery evidence is irrelevant because the  
3 G2, not the Recovery, was the predicate device for the Eclipse IVC filter that is the  
4 subject of this case. While nominally accurate, Bard ignores the fact that the Eclipse filter  
5 effectively *is* the G2 filter – it is the exact design of the G2 with a retrieval hook and  
6 electropolishing. Bard also ignores [REDACTED]  
7 [REDACTED]. See Booker Trial Transcript, Mar. 22, 2018,  
8 Ex. A, testimony of Robert Carr, at 1101:5-8 ([REDACTED]).

9 The fundamental flaw in Bard’s argument is its suggestion that the Eclipse is a  
10 different device than the G2; it is not. Bard’s own witnesses have testified that the  
11 “design change” to the Eclipse was essentially a marketing ploy and did not actually  
12 address complications experienced by the G2 (and G2X) and earlier by the Recovery.  
13 Abithal Raji-Kubba, Bard’s Vice President of Research and Development over the  
14 Eclipse, testified [REDACTED]  
15 [REDACTED]. See deposition  
16 of A. Raji-Kubba, dated July 18, 2016, Ex. B (“Raji-Kubba Dep.”), at 116:22-117:5,  
17 167:18-22. Other Bard witnesses testified consistently. See deposition of Michael  
18 Randall as Rule 30(b)(6) designee of Bard re Meridian & Denali filters, dated Jan. 18,  
19 2017, Ex. C, at 72:24-73:8; deposition of William Little, dated July 27, 2016, Ex. D, at  
20 24:9-25:3; deposition of Kimberly Romney, dated Jan. 18, 2017, Ex. E, at 185:17-21.

21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]. See Ex. B, Raji-Kubba Dep. at 173:5-16.  
24 [REDACTED]  
25 [REDACTED]  
26 [REDACTED]  
27 [REDACTED]  
28 [REDACTED]

1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 *Id.* at 167:19-168:8.

5 And despite public statements to the effect of improved fracture resistance,  
6 [REDACTED]  
7 [REDACTED]  
8 [REDACTED]  
9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]  
14 [REDACTED]  
15 [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED]  
22 [REDACTED]

23 Plaintiff's experts confirm the same thing. Robert McMeeking, Plaintiff's  
24 materials and design expert, will testify that "the Eclipse and the G2 Express filters are  
25 mechanically and materially identical." He will also testify that the core design problems  
26 with the G2 (and G2X), which originated in the Recovery, still exist with the Eclipse. The  
27 electropolishing did not address any of the actual design problems of the G2 or the  
28 Recovery. Dr. McMeeking will testify that, as with its changes from the Recovery to the

1 G2, Bard failed to follow best practices and standard industry procedures to determine the  
2 root cause for the fractures and other failures that G2 and G2X were experiencing.

3 [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]  
7 [REDACTED]  
8 Thus, Plaintiff will present evidence that because the Eclipse suffered from the  
9 same design defects as the Recovery and the Eclipse, it predictably resulted in the same  
10 types of failures as those two predicate devices. Plaintiff will also present evidence that  
11 Bard's design, development, and failure to take actions with respect to the Recovery  
12 resulted in the design defects in both the G2 and the Eclipse. In particular, as a result of  
13 Bard's failure to follow proper design standards and to conduct appropriate testing, the  
14 Recovery suffered significant and catastrophic failures when released to the market. In  
15 response, Bard chose to redesign the Recovery as the G2 (the same design as the Eclipse)  
16 but failed to determine the root cause for the Recovery's failure and failed again to  
17 conduct proper testing of the G2 to ensure that it adequately addressed the problems of the  
18 Recovery. Thus, the design problems with the Eclipse (like the G2) are directly traceable  
19 to Bard's actions and failures with the "standard design" for its retrievable filters.

20 The Recovery filter's development, complications, and deaths are relevant not only  
21 to Plaintiff's design defect and warning claims, but also her claim for punitive damages.  
22 For the reasons that evidence was relevant in *Booker*, it is likewise relevant here. And,  
23 evidence will show that [REDACTED]

1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED] is relevant to all of Plaintiff's causes of action  
5 inextricably intertwined with the filter story she will present at trial.

6 **II. Cephalad Migration Death Evidence is Not Unfairly Prejudicial**

7 Nor should evidence of Recovery cephalad migration deaths be excluded under  
8 Rule 403. Any prejudice resulting from the evidence is not undue, and the jury can be  
9 trusted to understand where the Recovery fits in the filter progression and the differences  
10 and similarities between the Recovery, G2, and Eclipse. [REDACTED]  
11 [REDACTED]  
12 [REDACTED]

13 [REDACTED] As in *Booker*, Defendants can argue to the jury why it  
14 should disregard such evidence. But the evidence is relevant and not unduly or unfairly  
15 prejudicial, and Plaintiff should be allowed to present the competent evidence she believes  
16 supports her claims in the manner she wishes, subject to the Court's time limitations.

17 **III. The FDA Warning Letter Remains Relevant and Appropriate in *Jones***

18 The limited evidence concerning Item No. 3 of the FDA warning letter the Court  
19 admitted into evidence in *Booker* is relevant in this case. See Plaintiff's Additional  
20 Briefing regarding Admissibility of Topics 3, 7, and 8 of FDA 483 Warning Letter Issues  
21 July 13, 2015, Doc. 10520. As the Court will recall, Bard's presentation of FDA evidence  
22 in *Booker* included memoranda documenting contact with the FDA as if FDA authorized  
23 all of Bard's actions described in those memoranda. And the jury instruction on design  
24 defect allowed the jury to consider FDA clearance, action and inaction relating to the  
25 device. Assuming the same or similar instruction is going to be given in *Jones*, then  
26 fairness requires that Plaintiff be allowed to present evidence of the FDA expressing  
27 concern with Bard's actions and directing it to take corrective action.  
28

1 Similar to Plaintiff's supplemental filing during the *Booker* trial, [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 Violation of federal statutes are relevant to Ms. Jones' design defect claim and is

10 relevant to punitive conduct. Moreover, as stated above [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 **IV. Conclusion**

20 For these reasons, Defendants' request to exclude Recovery filter and FDA

21 Warning Letter evidence should be denied.

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<sup>1</sup> Seven of the eight complaints listed in paragraph 3(c) are Eclipse filters.

1 RESPECTFULLY SUBMITTED this 12<sup>th</sup> day of April 2018.

2 GALLAGHER & KENNEDY, P.A.

3 By: /s/ Mark O'Connor

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 12<sup>th</sup> day of April, 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Jessica Gallentine